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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/822,850	04/09/2004	Michael John Dunkley	0198.00	2666

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EXAMINER	
ALI, SHUMAYA B	
ART UNIT	**PAPER NUMBER**
3771	

MAIL DATE	DELIVERY MODE
08/22/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/822,850	DUNKLEY ET AL.	
	Examiner	Art Unit	
	Shumaya B. Ali	3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 May 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-26 and 28-30* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9,13,25,27 and 28* is/are rejected.

7)☒ Claim(s) *10-12,26,29,30* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

Examiner grants this office action in response to the amendment filed on 5/22/07. Currently, claims 1-26, and 28-30 are pending in the application. Claims 1,14,19,24, and 28 have been amended and claims 27 and 31 have been cancelled.

Claim Objections

Claim 14 is objected to because of the following informalities: in lines 4 and 5, "the air inlets" lack antecedent basis. Appropriate correction is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-9, and 13-23 are rejected under 35 U.S.C. 102(e) as being anticipated by Helgesson et al US 6,892,728B2.

As to claim 1, Helgesson discloses a handheld aerosolization apparatus **(see figs. 1-22)** comprising a housing **(2)** defining a chamber **(space inside housing 2)** having a plurality of air

inlets **(38,39)**, the chamber being sized to receive a receptacle **(5)** which contains an aerosolizable pharmaceutical formulation; a shield **(64 and 22)** which covers at least one but not all of the air inlets, whereby the shield prevents blockage of the at least one air inlet by a user grasping the apparatus **(see fig.15)**, and an end section **(17)** associated with the housing, the end section sized and shaped to be received in a user's mouth or nose so that the user may inhale though the end section to aerosolize the pharmaceutical formulation and to inhale aerosolized pharmaceutical formulation that has exited the receptacle **(Helgesson disclose that air coming from inlets 38 and 39 lift the substrate/pharmaceutical formulation to be inhaled in to the dispersion chamber 18 ready for inhalation (see col.9, lines 65-68). Thus, air rushing though the inlets inherently aerosolizes pharmaceutical contents in the inhaler and once the formulation is in the dispersion chamber, it further gets aerosolized by the user's inhalation suction force).**

As to claims 2,15, and 20, Helgesson discloses wherein the shield is a portion of the end section **(see fig.15).**

As to claim 14, Helgesson discloses a handheld aerosolization apparatus **(see figs. 1-22)** comprising a housing **(2)** defining a chamber **(space inside housing 2)** being sized to receive a receptacle **(5)** which contains an aerosolizable pharmaceutical formulation; a shield **(64 and 22)** which covers a portion of but not all of at least one of the air inlets **(see fig.15)**, and an end section **(17)** associated with the housing, the end section sized and shaped to be received in user's mouth or nose so that the user may inhale through the end section to aerosolize the pharmaceutical formulation and to inhale aerosolized pharmaceutical formulation that has exited the receptacle **(Helgesson disclose that air coming from inlets 38 and 39 lift the**

substrate/pharmaceutical formulation to be inhaled in to the dispersion chamber 18 ready for inhalation (see col.9, lines 65-68). Thus, air rushing though the inlets inherently aerosolizes pharmaceutical contents in the inhaler and once the formulation is in the dispersion chamber, it further gets aerosolized by the user's inhalation suction force).

As to claims 3,16, and 21, Helgesson discloses wherein the end section is removably connected to the housing and wherein the end section may be removed from the housing to provide access to the chamber **(see fig.1, col.5 lines 52-67).**

As to claims 4,17, and 22, Helgesson discloses wherein the shield is a portion of the end section **(see fig.15).**

As to claim 5, Helgesson discloses wherein the shield comprises at least two covering portions **(64 and 22)**, each covering portion covering at least on inlet **(shield 64 has air inlets 66, and shield 22 has air inlets 30and 31).**

As to claim 6, Helgesson discloses wherein there are two covering portions and wherein the two covering portions are diametrically opposed **(see fig.15).**

As to claim 7, Helgesson discloses wherein the at least two covering portions are separated by open portions **(see figs.1 and 15).**

As to claim 8, Helgesson discloses wherein the open portions provide direct access to at least one inlet **(see figs. 1 and 15).**

As to claim 9, Helgesson discloses wherein the shield extends longitudinally along the apparatus **(see figs. 1 and 15).**

As to claims 13,18, and 23, Helgesson discloses wherein the inlet is shaped to create a swirling airflow within the chamber **(swirling effect is caused by the dispersion 18 and suction 19 chambers).**

As to claim 19, Helgesson discloses a handheld aerosolization apparatus **(see figs. 1-22)** comprising: a housing **(2)** defining a chamber **(space within 2)** having one or more air inlets **(38,39)**, the chamber being sized to receive a receptacle **(5)** which contains an aerosolizable pharmaceutical formulation; a shield **(64 and 22)** extending around only a portion of transverse circumference of the housing, the shield covering at least one air inlets, whereby the shield prevents blockage of the at least one air inlet by a user grasping the apparatus **(see fig.15)**; and an end section **(17)** associated with the housing, the end section sized and shaped to be received in a user's mouth or nose so that the user may inhale through the end section to aerosolize the pharmaceutical formulation and to inhale aerosolized, pharmaceutical formulation that has exited the receptacle **(Helgesson disclose that air coming from inlets 38 and 39 lift the substrate/pharmaceutical formulation to be inhaled in to the dispersion chamber 18 ready for inhalation (see col.9, lines 65-68). Thus, air rushing though the inlets inherently aerosolizes pharmaceutical contents in the inhaler and once the formulation is in the dispersion chamber, it further gets aerosolized by the user's inhalation suction force).**

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject

matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 24,25, and 28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Helgesson et al US 6,892,728B2.

As to claims 24,25,28,29, and 31, Helgesson lacks a detailed description of the claimed steps, however discloses an apparatus that is fully capable of providing the method steps of claims 24,25,28,29, and 31 **(see above rejection cited for claims 1-10,13, and 14-23).** Thus, the method steps as cited in claims 24,25,28,29, and 31 would have been an obvious result of using the apparatus of Helgesson.

Allowable Subject Matter

Claims 10-12,26,29, and 30 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Response to Arguments

Applicant's arguments filed 5/22/07 have been fully considered but they are not persuasive. Applicant argues that Helgesson does not anticipate claim 1-9, and 13-23 since he does not disclose the pharmaceutical formulation is not aerosolized from the receptacle by using the user's inhalation (see remark filed on 5/22/07, page 6, liens 24 and 25). This argument however is not well taken because Helgesson disclose air inlets 38 and 39 that lift the substrate/pharmaceutical formulation to be inhaled in to the dispersion chamber 18 ready for inhalation (see col.9, lines 65-68). Thus, air rushing though the inlets inherently aerosolizes pharmaceutical contents in the inhaler and once the formulation is in the dispersion chamber, the user's inhalation suction force further aerosolizes it. Thus, Helgesson anticipates claims 1-9, and 13-23.

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shumaya B. Ali whose telephone number is 571-272-6088. The examiner can normally be reached on M-W-F 8:30am-5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on 571-272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would

like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

8/19/2007

Shumaya B. Ali
Examiner
Art Unit 3771

JUSTINE R. YU
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 3700

8/20/07